

**ATT 34 ANDT**11343P-WO  
PCT/EP03/10630**10/529284**  
**JC17 Rec'd PCT/PTO 25 MAR 2005**

- 19 -

**Amended claims .**

1. A solid dosage form for oral administration  
comprising a coherent matrix with a disintegration time  
5 of less than 2 minutes, where

- the matrix comprises an active ingredient which is  
slightly soluble in a physiological fluid and  
which is in the form of fast-release micro- or  
10 nanocapsules,

- the micro- or nanocapsules comprise a core and a  
shell,

15 - the core comprises the slightly soluble active  
ingredient,

- the shell consists essentially of a material with  
high permeability for the slightly soluble active  
20 ingredient, and

- the shell of the micro- or nanocapsules comprises  
a complex of at least one polyelectrolyte and a  
counter ion to the polyelectrolyte.  
25

2. The dosage form as claimed in claim 1,  
characterized in that the matrix has a disintegration  
time of less than 30 seconds.

30 3. The dosage form as claimed in claim 1 or 2,  
characterized in that release of its active ingredient  
is virtually complete within 30 minutes.

4. The dosage form as claimed in any of the preceding  
35 claims, characterized in that it comprises gelatin and  
mannitol in a ratio of 1:1 to 1:3.

**INT. 24. 2007**11343P-WO  
PCT/EP03/10630

- 20 -

5. The dosage form as claimed in any of the preceding claims, characterized in that the slightly soluble active ingredient is an analgesic, a migraine remedy, a spasmolytic, an antiemetic, an antiallergic, an antidiarrheal, an antihypertensive, an antihypotensive, an antivertigo agent, a psychoactive drug, an antidote, habit cessation aid, an antiarrhythmic, a sedative, a hypnotic, a tocolytic, a diagnostic or a substance to counter erectile dysfunction.
6. The dosage form as claimed in any of the preceding claims, characterized in that the micro- or nanocapsules have an average particle size of not more than about 10  $\mu\text{m}$ .
7. The dosage form as claimed any of the preceding claims, characterized in that the counter ion is a polyelectrolyte.
8. The dosage form as claimed in any of the preceding claims, characterized in that the micro- or nanocapsules are produced by layered electrostatic self-assembly.
9. The dosage form as claimed in any of the preceding claims, characterized in that the shell of the micro- or nanocapsules comprises at least one lipid layer or lipid bilayer.
10. The dosage form as claimed in any of the preceding claims, characterized in that the matrix is produced by compressing a powder or granules.
11. The dosage form as claimed in any of claims 1 to 9, characterized in that the matrix is produced by freeze-drying a fluid or highly viscous composition.

ART 34 Amdt

11343P-WO  
PCT/EP03/10630

- 21 -

12. The dosage form as claimed in any of claims 1 to 9, characterized in that the matrix is produced by drying or solidifying a composition which has been extruded or spread out like a film.

5

13. A process for producing a dosage form as claimed in claim 1 or 10, characterized in that fast-release micro- or nanocapsules comprising a slightly soluble active ingredient are mixed and optionally granulated with matrix-forming, physiologically acceptable excipients, after which the mixture or the granules is or are compressed to tablets.

14. A process for producing a dosage form as claimed in claim 1 or 11, characterized in that fast-release micro- or nanocapsules comprising a slightly soluble active ingredient are mixed with matrix-forming, physiologically acceptable excipients and a liquid carrier to give a solution or suspension, after which the solution or suspension is divided up into dose units and freeze-dried.

15. A process for producing a dosage form as claimed in claim 1 or 12, characterized in that fast-release micro- or nanocapsules comprising a slightly soluble active ingredient are mixed with matrix-forming, physiologically acceptable excipients and a liquid carrier to give a solution or suspension, after which the solution or suspension is spread out like a film, dried and divided up into dose units.

16. The use of a dosage form as claimed in any of the preceding claims for producing a medicament for the treatment of acute diseases or symptoms.